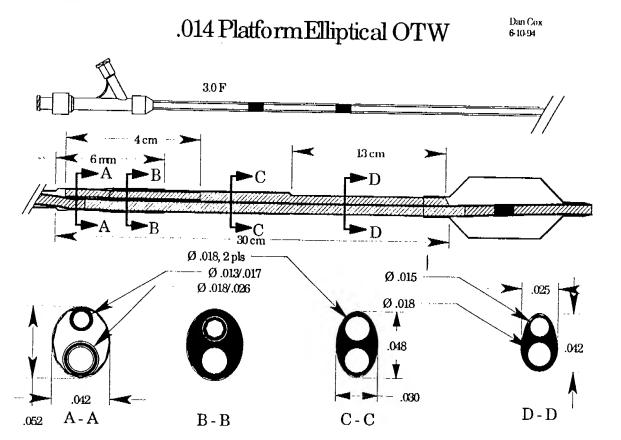
Exhibit 35

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ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

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ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

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		in wire		N/A	

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Date:

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Title:

Coax w/PEEK - Elliptical Distal (with a 100% HDPE a 75/25 HDPE/LLDPE and a 83/13/4 HDPE/LLDPE/GRAPHITE distal elliptical)

Objective:

To evaluate these catheters to determine if the stiffer materials

(100%HDPE and 83%/13% 4% HDPE/LLDPE/GRAPHITE) perform better than

the softer 75/25 material. I.e., prevent prolaspe

Procedure:

Note: Ref drawing for dimensions

Tooling:

.011, .017, .018, .024, .026, .028 .031 and .040 Teflon coated mandrels.

.025, .031, .039, 043 and .048 Teflon capture tubing.

Razor blades, Hot box, and Induction heater

Materials:		
Description	Part Number	Comments
Elliptical dual lumen	N/A R&D	75/25 Alathon/LDPE
Elliptical dual lumen	Ext. # 10-465-T	100% HDPE
Elliptical dual lumen	Ext. # 12-194-B	83% HDPE w/13% LLDPE +
Emption dans identification		4% Graphite
ΙM	Ext. # 13-88-A	Graphite
Intermediate shaft	Ext. # 12-083	Alathon 6210
IM	Ext # V-466-1	Graphite
Stiff Shaft	Vendor# 02-149	PEEK 381G
Shaft adaption cup	MC500419-02	N/A
IM adaption cup	MC500296	Standard ACS part
Centerport	MC500323	Standard ACS part
Nose cone	MC500319	Standard ACS part
Two arm	RM500219	******
Distal tip Material	Ext # V-466-1	Graphite
Balloon	3.0mm Edge	PE 600
Shrink tubing	SA500082-03	
Gold Bands	RM500340	
Loctite	RM60563	414
• •	RM60124	420
Loctite	RM60562	350
Loctite	レブメブハウンハマ	<i>33</i> 0

Assembly Instructions: (Distal Elliptical)

- Cut approximately 40 cm of the elliptical shaped tubing.
 Place a .018" Teflon Mandrel in the guide wire lumen and a .015 Teflon mandrel in the inflation lumen.
- Neck the material down to .026 x .045 \pm .001.
- Parameters: Temp = 270°f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat = 5 Dwell Cool = 1 Length = 15cm Trim necked portion to 10cm.
- Cut a 2-3mm notch in the inflation lumen at the distal tip of the necked material. (fig 1)

Cut the graphite to approximately 20 cm.
Neck the graphite to .021 OD using an autonecker.
Parameters: Temp = 290° f Stretch Speed = 400 Nozzle Speed = 200 Length = 10cm

- Slide the gold band over the necked portion.

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- Recover the graphite up to the gold band using a .024 capture tube and Hot Box, at 350° f

Using a .028" sheath and a Hot Box at 350° f and 60-70 psi expand 1 cm. Remove material from the sheath and trim to 5mm.

- Insert a .017" Teflon mandrel through the graphite and the guidewire lumen of the elliptical material.

- Fuse the graphite to the elliptical dual lumen using a .026 capture tube and Hot Box at 350° f

Balloon Seal:

- Expand proximal balloon shaft in a .048 ID capture tube.

- Trim to 7mm

Insert a .015 mandrel into the inflation lumen.

Slide .039 oval split sheath onto catheter.

Slide sheath over proximal portion of the balloon and heat seal at 350° f

Flatten with a flat smooth block

Remove inflation/deflation mandrel.

Tip seal using a "Balloon Buncher Tip Sealer"

Parameters: Temp = 340' f Hot Stretch = 0003 Dwell = 0006 Pretension = 0006 Micrometer setting = 0.675"

Proximal End:

Trim assembly from the gold band to the proximal end of the elliptical shaped tubing 35cm.

Insert two-.018 Teflon coated mandrels into both lumens.

Neck using an autonecker.

- Parameters: Temp = 270'f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat = 5 Dwell Cool = $\hat{1}$ Length = 1.5cm (trim to 1cm)
- Remove the mandrels and Insert a 4.5cm piece of Polyimide into the inflation lumen. Tack the Polyimide into place with a drop of Loctite 420.

Inner Member Assembly:

Cut a 125cm piece of Graphite inner member material.

Insert a .017 mandrel through the Graphite.

- Neck the Graphite to .021 OD using an autonecker.

 Parameters: Temp = 290' f Stretch Speed = 400 Nozzle Speed = 200 Length = 1cm (trim to 4mm)
- Flare the guidewire lumen with a .025 mandrel 1mm.

Insert the necked graphite into the flared guidewire lumen.

Insert a .012 mandrel into the Polyimide.

- Bond the Graphite to the dual lumen elliptical material using a .039 oval capture tube or silicone
- Parameters: Temp = 350° f (Hot Box)
- Remove the .012 mandrel from the Polyimide.

Proximal Shaft Assembly:

Cut a 110cm piece of PEEK.

Expand one end of the PEEK, 1cm in a .043 capture tube using a Hot Box at 350° f (ID should be .039)

Trim the expanded portion 5-6mm

Cut the PEEK 102 cm from the proximal end of the expanded portion.

Slide the PEEK over the Graphite IM and elliptical material and bond using Loctite 420 Note: do not allow the adhesive to wick into the Polyimide tubing. Note: do not force the unexpanded PEEK over the Inflation lumen.

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Two-Arm Assembly:

Trim the graphite 3cm from the proximal end of the PEEK.

Slide the nosecone, outer member adaption cup, and twoarm over the PEEK.

Bond and inner member adaption cup to the graphite using 3.0 mm x 1cm shrink tubing on a Hot Box at 350° f. Note: use a .018 Teflon mandrel in the graphite.

- Attach the IM cup to the twoarm with a centerport

- Slide the outer member cup up toward the twoarm and wick in UV cure Loctite 350

- Attach the OM cup to the twoarm and tighten the nosecone and centerport

- UV cure on each side of the nosecone for 50 seconds.

Final Assembly:

- Trim tip to 3.0mm

- Tip Sand

- Microglide and Sheath

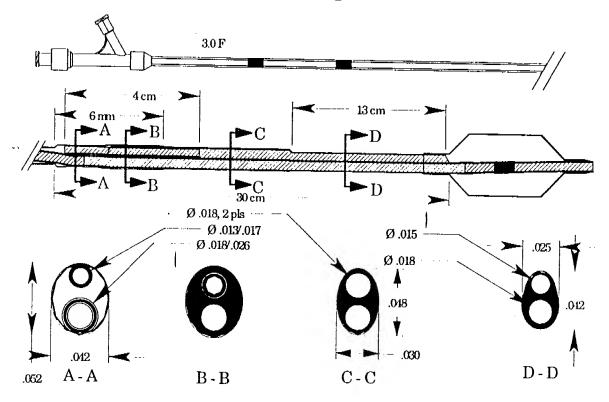
Conclusion: The 100% HDPE and the 83/13/4 blend performed better than the 75/25 LLDPE catheters. The 83/13/4 blend tracked over the wire with ease. It was mentioned that "this is the best I have seen in a while" the guidewire movement was rated 3.75 on a scale of 1 -5 with 5 being the best. Both the 100% and the 83/13/4% blend had good push however the 100% was slightly better. The 100% HDPE and the 83/13/4% blend seem to follow the wire and was less prone to prolapsing whereas the 75/25% seem to press up against the walls of the artery. (for more details see heart model evaluation notes)

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.014 Platform Elliptical OTW

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ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

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ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

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ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

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Mary 6/24/94

(See Reverse)

white

S.	Ease of prep:	Preg method:				
		Significantly Sector C	Serrywne Seter O	Same As O	Semeurat Worse G	Sign al Caraly Worse O
	Comments:					
3 .	inflation and deflation times;	Symicarity Setur O	Server O	Same As	Sarrana Warne O	Squicanty Worse O
		Infation time:	<u>. </u>	Defance	t tathet:	
		Contrast & diluxor	n:	Indation	device:	
	Comments;	*	· · · · · · · · · · · · · · · · · · ·	 		
7.	General appearance of dilatation catheter during inflation and deflation (note bowing and folding):	Septembr Seter O	Santa-Free Beder O	Same As G	Şaiflewfulk Worse O	Significarwy Wome O
* *	Солителя:			<u> </u>	#1.100	
			. <u>-</u> .		· · · · · · ·	
a.	Trackability:	Sgraficaraty Better O	Special Special C	Serre As	Someone Warten	S ignificantly Works ©
	comments: About race as	D Not a	s good a	(Z)		
9.	Pusnaoility:	Synformy Beter C	Somewhat Sector O	Same As	Somewhat Wares	Significantly Warse O
	commens: Push is protty	god Oc	esn't squar	e off in v	ocel like	1 when
10,	Guide beck out:	<u> </u>	Yes		No	
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11.	Guide wire movement;	Signaturally Began	Server Server	Same As	Someone Waren	Significantly Works C
	commons Pretty good.	3.75 h	septal.	•		
12	Olmensions (list size and area):					
14	Difference (list Mar sint area).					
						
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13.	Old product meet design goals?		Yes	- · · · · · · · · · · · · · · · · · · ·	Me	
	rail comments: acted well to 037 le tery when pushing aga	sion in die linst lesion	igaral, but	catheter	squamed o	CP in
		Recommend	For Animal Studie	1 ?		
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PROPERTY OF ADVANCED CARDIOVASCULAR SYSTEMS, INC.



Advanced Cardiovascular Systems, Inc. 3200 Lakeside Drive

P.O. Box 58167

Santa Clara, CA 95052-8167

NAME <u>ERIC</u> DEPT. _ 1220 LAB. NOTEBOOK NO. ISSUE DATE -RETURN DATE -

RETURN TO DOCUMENT CONTROL FOR ARCHIVING.

5/25/94

Title:

Shaft Material Evaluation

Objective:

To evaluate various potential shaft materials

Materials:

EVAL Extrusion # 12-143A, EVAL Extrusion # 12-142A, AERN Nylon Ext # 11-221-1, Grivory Nylon Ext # 10-547-6, Grivory Nylon Ext # 10-548-1, PPS Ext # 10-556-1, Isoplast Ext # 10-531-1, PEEK 381G and PES Ext# 10-576-1

Procedure:

Rupture test 10 samples of the EVAL material and 5 samples each of the other materials. Parameters:

Water Temp=37degC, Start Pressure=60psi, Increments=15psi, Hold time=15sec

Results:

Material	Ext #	IDV00	Average Ru	ot .	Std Dev	!	T		
EVAL	12-143A	.017/.021			14.5773	81	 		1
EVAL		.032/.038			6.324555		 		+
AERN NYLON		.031/.038			8.215838		 		+
GRIVORY NYLO			 		8.215838			+	
GRIVORY NYLO					8.215838		 		
ISOPLAT	10-531-1	.031/.038	1		16.43167		-	 -	+
PPS		.031/.038			8.215838-		 		
PES		.032/.039		500)	 		+
PEEK	N/A	.032/.038		500)i			-
Material	Sample #	Duan-	Material		S	l D			
EVAL (Inner Men			EVAL		Sample #	Rupaire	Material	Sample #	
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	8	210					+	7	
	9	225			8			8	
	10	225	 		10			9	
	10		┿	i		120	 	10	<u> </u>
Material	Sample #	Rupture	Material	1:	Sample #	Rupeare	Material	Sample #	Ruome
GRIVORY 547	1	405	GRIVORY	548	1	500	PEEK	1	
	2	420		T	2	500		2	
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	41	420	1		4	500		4	
	5	420	-	_	5	500		5	500
				1					
				-					
fateriaj	Sample #1	Кироле	Material	!	ample#	Rupture	Material	Sample #	Runner
SOPLAT	1/	375	PPS		ı.	405	PES	1	500
	2	375		-1	2	405	T	2!	500
	31	405		ĺ	31	420		3	500
		405		T	4	420		4	500
	5	375		- ;	56	405	1	51	500

Date:

5/27/94

Title:

PEEK To Elliptical Transition Development

Objective:

To evaluate various concepts for improving the transition from the PEEK outer

shaft to the elliptical distal dual lumen.

Materials:

Graphite Extrusion V-466-1, PEEK 3816, HDPE SA200247, Alethon Extrusion

12-083, Stainless Steel .007>.003 mandrels, Polyimide "Hudson" .013 x .017,

and Loctite 414

Procedure:

Concept 1

PEEK to Elliptical. Insert two .018 Teflon coated mandrels into the elliptical tubing and neck using a hot box at 350F. Trim the necked portion to 5mm remove one of the mandrels and insert a 4 cm piece of polyimide tubing inside that lumen, wick in some adhesive to hold it in place. Bond the graphite to the other lumen with a but joint using an .026>.042 step sheath at 350f. Flare one end of the PEEK to an ID that will allow it to fit over the necked elliptical tubing. Trim the PEEK to 5mm and bond it to the elliptical tubing using Loctite 414.

Concept 2

PEEK to Elliptical with Intermediate Shaft. Insert two .018 Teflon coated mandrels into the elliptical tubing and neck using a hot box at 350F. Trim the necked portion to 5mm remove one of the mandrels and insert a 4 cm piece of polyimide tubing inside that lumen, wick in some adhesive to hold it in place. Bond the graphite to the other lumen with a but joint using an .026>.042 step sheath at 350f Cut a 3cm piece of HDPE flare one end so that it fits over the elliptical tubing. Using a .045 Teflon capture tube heat bond the HDPE to the elliptical tubing. Flare one end of the PEEK to an ID that will allow it to fit over the HDPE. Trim the PEEK to 5mm and bond it to the elliptical tubing using Loctite 414.

Concept 3
PEEK to Elliptical with .007>.003 tapered mandrel in the inflation lumen. Insert two .018 Teffon coated mandrels into the elliptical tubing and neck using a hot box at 350F trim to 5mm remove mandrel from one of the lumens and insert a 4 cm of tapered mandrel inside that lumen wick in some adhesive to hold it in place. Bond the graphite to the other lumen with a but joint using an .026>.042 step sheath at 350f. Flare one end of the PEEK to an ID that will allow it to fit over the necked elliptical tubing. Trim the PEEK to 5mm and bond it to the elliptical tubing using Loctite 414.

Conclusion:

Concept 1 was easily assembled and had a fairly good transition from PEEK to elliptical due primarily to the Polyimide in the inflation lumen; the joint was smooth and had an OD of .040x.046. Concept 2 required additional steps to build and yet it was inconclusive about which had a better transition. The OD measured .040x.047. Concept 3 had an improved transition over the first two however it was far more difficult to assemble and the wire was too large and could possibly impede

deflation.

Date:

5/27/94

Title:

PEEK to Elliptical Intermediate vs No Intermediate Shaft

Objective:

To compare and evaluate the performance of a PEEK to elliptical OTW catheter with and

without a intermediate shaft.

Procedure:

Tooling:

.011, .017, .018, .024, .026, .028 .031 and .040 Teflon coated mandrels. .025, .031, .039, .043 and .048 Teflon capture tubing.

Razor blades, Hot box, and Induction heater

Materials: Comments Part Number Description 75/25 Alathon/LDPE Ext # 12-110A-Elliptical dual lumen Alathon 6210 Ext # 12-083 Intermediate shaft Ext. # V-466-1 Graphite IM PEÉK 381G Vendor# 02-149 Stiff Shaft N/A MC500419-02 Shaft adaption cup Standard ACS part Standard ACS part Standard ACS part MC500296 IM adaption cup MC500323 MC500319 Centerport Nose cone RM500219 Two arm Graphite Ext # V-466-1 Distal tip Material PE 600 3.0mm Edge Balloon SA500082-03 Shrink tubing RM500340 Gold Bands 414 RM60563 Loctite 420 RM60124 Locute 350 RM60562 Loctite

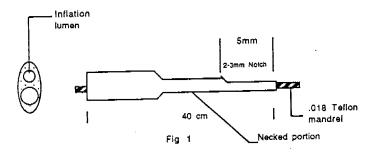
Assembly Instructions: (Distal Elliptical)

Cut approximately 40 cm of the elliptical shaped tubing.

Place a .018" Teflon Mandrel in the guide wire lumen and a .015 Teflon mandrel in the inflation lumen. Neck the material down to .026 x .045 +/- .001.

Parameters: Temp = 270'f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat = 5 Dwell

Cool = 1 Length = 15cm Trim necked portion to 10cm.
Cut a 2-3mm notch in the inflation lumen at the distal tip of the necked material. (fig 1)



Distal Tip:

Cut the graphite to approximately 20 cm.

Neck the graphite to .021 OD using an autonecker.

Parameters: Temp = 290 f Stretch Speed = 400 Nozzle Speed = 200 Length = 10cm

Slide the gold band over the necked portion.

Recover the graphite up to the gold band using a .024 capture tube and Hot Box, at 350° f

- Using a .028" sheath and a Hot Box at 350° f and 60-70 psi expand 1 cm. Remove material from the sheath and trim to 5mm.

- Insert a .017" Teflon mandrel through the graphite and the guidewire lumen of the elliptical material.

- Fuse the graphite to the elliptical dual lumen using a .026 capture tube and Hot Box at 350° f

Expand proximal balloon shaft in a .048 ID capture tube.

- Trim to 7mm

Insert a .015 mandrel into the inflation lumen.

Slide .039 oval split sheath onto catheter,

Slide sheath over proximal portion of the balloon and heat seal at 350° f

Remove inflation/deflation mandrel.

Tip seal using a "Balloon Buncher Tip Sealer"

- Parameters: Temp = 340° f Hot Stretch = 0003 Dwell = 0006 Pretension = 0006 Micrometer setting = 0.675"

Proximal End:

Trim assembly from the gold band to the proximal end of the elliptical shaped tubing 35cm.

Insert two-.018 Teflon coated mandrels into both lumens.

Neck using an autonecker.

- Parameters: Temp = 270 f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat = 5 Dwell Cool = 1 Length = 1.5cm (trim to 1cm)
- Remove the mandrels and Insert a 4.5cm piece of polyimide into the inflation lumen. Tack the polyimide into place with a drop of Loctite 420.

Inner Member Assembly:

Cut a 160cm piece of Graphite inner member material.

Insert a .017 mandrel through the Graphite.

 Neck the Graphite to .021 OD using an autonecker.
 Parameters: Temp = 290° f Stretch Speed = 400 Nozzle Speed = 200 Length = 1cm (trim to 4mm)

Flare the guidewire lumen with a .025 mandrel 1mm.

Insert the necked graphite into the flared guidewire lumen.

Insert a .012 mandrel into the polyimide.

Bond the Graphite to the dual lumen elliptical material using a .039 oval capture tube or silicone gel mbing. Parameters: Temp = 350° f (Hot Box)

- Remove the .012 mandrel from the polyimide.

Proximal Shaft Assembly:

Cut a 110cm piece of PEEK

Expand one end of the PEEK, 1cm in a .043 capture tube using a Hot Box at 350° f (ID should be .039)

Trim the expanded portion 5-6mm

Cut the PEEK 102 cm from the proximal end of the expanded portion.

Slide the PEEK over the Graphite IM and elliptical material and bond using Loctite 420 Note: do not allow the adhesive to wick into the polyimide tubing. Note: do not force the unexpanded PEEK over the Inflation lumen.

Two-Arm Assembly: - Trim the graphite 3cm from the proximal end of the PEEK.
- Slide the nosecone, outer member adaption cup, and twoarm over the PEEK.
- Bond and inner member adaption cup to the graphite using 3.0 mm x 1cm shrink tubing on a Hot Box at 350° f. Note: use a .018 Teflon mandrel in the graphite. Attach the IM cup to the twoarm with a centerport. - Slide the outer member cup up toward the twoarm and wick in UV cure Loctite 350 - Attach the OM cup to the twoarm and tighten the nosecone and centerport - UV cure on each side of the nosecone for 50 seconds. Final Assembly: - Trim tip to 3.0mm - Tip Sand - Microglide and Sheath Conclusion: Note: the Catheters built with an intermediate shaft were built by Kim Nugyen ref Lab notebook # 1152. The Catheters were compared in a heart model and it was determined that there was little difference in the two catheters performance, however neither catheter performed very well in comparison to our coaxial design. The proximal balloon seals were perceived as stiff and having an abrupt transition. Recommendation: Rebuild using the "no intermediate shaft" and improve the proximal balloon seal stiffness Recommendation: Repulse in a heart model. REF: heart Model Results NEXT Pasa 2.W 1-15-94 2/2/(af



ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

Product 014 Platform C		Date:	5/20/94	<u> </u>	
Project Engineer: Dam			Wet:	The state of the s	
Clinical Research Coordinator	<u>Ron</u> Se	ma		and the second	Ory .
Guiding Catheter 7F JL	4 PG	Guide: V	Vīre::::		
Product design/performance goals:					
Coaxial OTW PE Alapan 6210 distal sha	EK prima Ft 2.7 F p	1 outer 5 DEGOO 3.0	haft graph	Je PE in	nty men
. Tip softness:					
	Significantly Bester C	Somewag Segar O	Same As	Sorteung Wares	Synica
comments Nice taper	SMCcTh				
Tip length;	Significantly Better	Software; Secur	Same As	Samurag	Syrian
Comments.		<u> </u>	•	0	- Wesse
Smoothness of transition:					
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Nice Folding	Better O	3ecur O	Semo As	Worm	Significant Wares
a Balloon to snam: Can feel trunsition	Significantly Setter	Santouring Botter	Same As	Sattemenge	Systems Systems
C. Shalt transitions:	•	•	٥	0	3
Can Feel AEEX/AE junction	Becar	Somewhat Sector	Same As	Somewhat Words O	S prince Warne
Commence Transitions notice	eable but	not a prob	len		
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3. Distal shart	Significantly	Someone	0	Some	9
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	Significantly Better	Sorgi-ner Boowr	Same 4-	Servera	Systemy
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A1 /	Contrast & dilution:		Deflation		
comments: No bowing					
General appearance of diletation	Sondowe				
catheter during inflation and deflation (note bowing and folding):	Setter O	3	Same As	Seme-res Wares O	Signalizaray Wares
Comments:			 	<u> </u>	
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Comments: TIP came arou	al bend nic	ely. Too	k contour	of wire.	nicely
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1/2	Berry O	Seator O	Same As	Someway Warse O	Signalicanay Wares
and with support got	all the way	60 sec 1	no support	got 70%	into lesion (
Guide back out:		Yes			
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t to kink and prolopse	like (2) ex	expt a 1	of more	1, Pazalt to	grolapse
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ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

	ulding Catheter		Guide: W	1.5		
Pre	oduct design/performance goals:	. (م حل م	CL .	1 00 1	1	-
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1.	Tip softness:	Significantly Better	Somewhat Setter	Same As	Streeting Warse	Significa
	Comments:			<u>y</u>		-
2	Tip length:	Sign ifica ay Beter	Somewhat Sector	Serte	Serrounes Worse	Significan
	Comments:				<u></u>	· · · · · ·
	Smoothness of transition:					
k	A. Distal to to balloon: lot as nice as D in fold	Significandy Setter	Somewhat Senter	Sayrier Ag	Somewhat Worse	Significan Worse
5~	3. Salloon to share neother tran () but bulky of Shart manager to shaff	Significantly Compared Sector	Someonia Beter C	Same As	Sammeng Worke	G Significant Manual
	C. Shart transmoons: To shaffs Nice, smooth	Significancy Better	Somewhee	Santo As	Somewhat	Serien
	Comments: B	-	X in abrupt	ness, not alo	+	Worse
	Flexibility of shart;					
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	B. Cistal snart	Significancy Better	Somewhat deter	Q Same As	O Sommonia Worse	Significants
	Comments: B: A little more	florix 1-			0	· 3

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	balloon into 045 lesion. Go	it all the w	av in with	quide supp	n -+	7/80/ 6/
			3 227701	3000	<u> </u>	
10.	Guide back out:		Y==			
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	4	, 0	, 0	, a	. 3	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
	Commence: Lightly seated ju	nt got ha n	to lesion (o	<u>43)</u>		
	- J					
11.	Guide wire movement;	Significancy	Samonnag		Somewag	Sylvicia
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12. (Olmensions (list size and area);					
						
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13. 0	Old product meet design goals?	<u>-</u>	Y==		No	
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ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

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GIII	ding Catheter		Guide: Win			t disp.
	suct design/performance goals:	- '(1	- r. L-	01-6 -1-8	eret hat	Jeno
<u>54</u>	ame as (2) except h	DEEK 3.0 m	- РЕ600	HIAIM SIII	rspan / O.E./	
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1.	Tip softness:	Sgriftcerity Beter	Sermulat Sector C)	Same As Q	Servenium Warme C	Signals Ward
• 1	comments Nice taper	<u> </u>				
2.	Tip length:	Significantly	Samura	Same At	Spender	Signation
_		Bester O	3		9	9
	comments A little shor	ter				
3.	Smoothness of transition:					
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ļ	3. Balloon to snaft	Significantly Separ	Same	Same As	Sampung Warns	Sonia
	Like 🖾	0	3	9	×	- C
	C. Shart transitions:	Signalesenty Better O	Sommeret Senter O	Same As	Somermer Wares O	Signal West
	comments C Both transit	ons are nice o	and smooth	More sub	Ha surtah	<u> </u>
	to elliptical. PEEK to	PE Fook like (I), PE to ell	ptical is nice		
4.	Flexibility of shaft:				C	Conti
	A, Proximal shart:	Sig rafica dy Seter C	Somewhile Sozer	Same As O	Worse	V40s
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	Comments:		<u></u>		·····	
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5.	inflation and deflation times:	Significantly Sector	Saffermed Bester 'Cl	Santo As	Safferency Warne	Signatural
		Inflation time:		Derlazion	tume: 12 Sec	hard to se
	2	Contrast & dilution:	; <u></u>	Inflation	device:	
	Comments: Same	<u>-</u>	·	· · · · · · · · · · · · · · · · · · ·		
_						······································
7.	General appearance of diletation catheter during inflation and deflation	Significantly Bester	Sememer Beter	Sarra As	Someonia Warter	Significantly Warms
	(note bowing and folding):	Inner ment	o oer rides	side of E	3 ' 11 /	n 1
	Comments: DOMP bowling	Loner ment	riales	MAP OF E	balloon at	Ratm.
-	Trackability:	Significantly	S	-		
	··,·	Setter	Berer	Same As	Worse	Signal Country Wildren
	Comments:					
			-			
	Pushability:	Significantly Setter	Samoures Bester	Same As	Someone	Signal Carriery Waterson
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		nsed into cij			w push	₩ 13/A/
).	Guide back out:	····	Y==	<u> </u>	He	
		Significantly	Saranas		Someway	- Symbolog
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Date:

6/21/94

Title:

Coax w/PEEK - Elliptical

Objective:

To evaluate these catheters (with improved proximal balloon seal and

guidewire movement) versus the catheters in the previous heart model. Ref pg.

Procedure: Note: Ref drawing for dimensions

Tooling:

.011, .017, .018, .024, .026, .028 .031 and .040 Teflon coated mandrels.

.025, .031, .039, 043 and .048 Teflon capture tubing.

Razor blades, Hot box, and Induction heater

Materials:

Comments Part Number Description 75/25 Alathon/LDPE Elliptical dual lumen N/A R&D Ext. # 12-083 Alathon 6210 Intermediate shaft Ext # V-466-1 Graphite IM PEÉK 381G Stiff Shaft Vendor# 02-149 N/A MC500419-02 Shaft adaption cup Standard ACS part IM adaption cup Standard ACS part MC500323 Centerport MC500319 Standard ACS part Nose cone RM500219 Two arm Ext. # V-466-1 Graphite Distal tip Material PE 600 Balloon 3.0mm Edge Shrink tubing SA500082-03 RM500340 Gold Bands Loctite RM60563 414 420 RM60124 Loctite 350 RM60562 Loctite

Assembly Instructions: (Distal Elliptical)

Cut approximately 40 cm of the elliptical shaped tubing.

- Place a .018" Teflon Mandrel in the guide wire lumen and a .015 Teflon mandrel in the inflation lumen.
- Neck the material down to $.026 \times .045 +/- .001$.
- Parameters: Temp = 270°f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat = 5 Dwell Cool = 1 Length = 15cm Trim necked portion to 10cm.
- Cut a 2-3mm notch in the inflation lumen at the distal tip of the necked material. (fig 1)

Distal Tip:

Cut the graphite to approximately 20 cm.

Neck the graphite to .021 OD using an autonecker.

Parameters: Temp = 290' f Stretch Speed = 400 Nozzle Speed = 200 Length = 10cm

Slide the gold band over the necked portion.

- Recover the graphite up to the gold band using a .024 capture tube and Hot Box, at 350° f Using a .028" sheath and a Hot Box at 350° f and 60-70 psi expand 1 cm. Remove material from the sheath and trim to 5mm.
- Insert a .017" Teflon mandrel through the graphite and the guidewire lumen of the elliptical material.
- Fuse the graphite to the elliptical dual lumen using a .026 capture tube and Hot Box at 350° f

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Balloon Seal:

Expand proximal balloon shaft in a .048 ID capture tube.

Trim to 7mm

Insert a .015 mandrel into the inflation lumen.

Slide .039 oval split sheath onto catheter.

Slide sheath over proximal portion of the balloon and heat seal at 350° f

Flatten with a flat smooth block

Remove inflation/deflation mandrel.

Tip seal using a "Balloon Buncher Tip Sealer"

Parameters: Temp = 340' f Hot Stretch = 0003 Dwell = 0006 Pretension =

Proximal End:

Trim assembly from the gold band to the proximal end of the elliptical shaped tubing 35cm. Insert two-.018 Teflon coated mandrels into both lumens.

Neck using an autonecker.

Parameters: Temp = 270°f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat

= 5 Dwell Cool = 1 Length = 1.5cm (trim to 1cm)

Remove the mandrels and Insert a 4.5cm piece of Polyimide into the inflation lumen. Tack the Polyimide into place with a drop of Loctite 420.

Inner Member Assembly:

Cut a 125cm piece of Graphite inner member material.

Insert a .017 mandrel through the Graphite.

- Neck the Graphite to .021 OD using an autonecker.

 Parameters: Temp = 290° f Stretch Speed = 400 Nozzle Speed = 200
- Flare the guidewire lumen with a .025 mandrel 1mm.

Insert the necked graphite into the flared guidewire lumen. Insert a .012 mandrel into the Polyimide.

- Bond the Graphite to the dual lumen elliptical material using a .039 oval capture tube or silicone Parameters: Temp = 350° f (Hot Box)

- Remove the .012 mandrel from the Polyimide.

Proximal Shaft Assembly:

Cut a 110cm piece of PEEK.

Expand one end of the PEEK, 1cm in a .043 capture tube using a Hot Box at 350° f (ID should

- Trim the expanded portion 5-6mm

Cut the PEEK 102 cm from the proximal end of the expanded portion.

Slide the PEEK over the Graphite IM and elliptical material and bond using Loctite 420 Note: do not allow the adhesive to wick into the Polyimide tubing. Note: do not force the unexpanded PEEK over the Inflation lumen.

Two-Arm Assembly:

Trim the graphite 3cm from the proximal end of the PEEK.

Slide the nosecone, outer member adaption cup, and twoarm over the PEEK.

Bond and inner member adaption cup to the graphite using 3.0 mm x 1cm shrink tubing on a Hot Box at 350° f. Note: use a .018 Teflon mandrel in the graphite.

Attach the IM cup to the twoarm with a centerport.

- Slide the outer member cup up toward the twoarm and wick in UV cure Loctite 350

Attach the OM cup to the twoarm and tighten the nosecone and centerport

UV cure on each side of the nosecone for 50 seconds.

Final Assembly:

Trim tip to 3.0mm

Tip Sand

Microglide and Sheath

Conclusion: These catheters performed better then the catheters in the previous heart model. The proximal seals were improved by maintaining a flat geometry. This was accomplished by using a smooth flat block to flatten the bond area while it's in the capture tube. Although these catheters were better then the previous elliptical units they were not as good as the coaxial and could use some improvements. The guidewire movement was better than before but again not as good as the coaxial. The catheters did not track as well and seem to prolapse in the Aorta when the guide was backed out and force was applied to the catheter.

Recommendation: It was recommended that we evaluate different materials transitions and dimensions to reduce the prolapsing. Refine the inner member junction to improve wire movement. Another heart model was tentatively scheduled. (see heart model evaluation notes)